

### **REMARKS**

This responds to the Office Action dated March 22, 2006. Claims 8 and 10 are amended. Claim 9 is canceled. No claims are added. As a result, claims 1, 3, 5, 7-8, 10-15, 17-27, 29-44 and 46-49 are now pending in this patent application.

#### **Information Disclosure Statement**

Applicant submitted an Information Disclosure Statement and a 1449 Form on November 21, 2003. Applicant respectfully requests that initialed copies of the 1449 forms be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner.

#### **§103 Rejection of the Claims**

1. Claims 1, 3, 8-14, 17, 19, 29 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S. Patent No. 5,154,171). Applicant respectfully traverses.

##### **Concerning claims 1 and 3:**

The Office Action admits that Levine does not teach use of ejection fraction. While Chirife apparently uses the ejection fraction, it does so for the purpose of controlling pacing rate in bradycardia patients who have too-slow heart rhythms and, therefore, need a pacemaker. (*See, e.g., Chirife at Abstract.*) Applicant can find nothing in Chirife that indicates that ejection fraction can be used for predicting the onset of a sudden cardiac death episode using trended data, as recited or incorporated in these claims. Similarly, Applicant can find nothing in Levine that indicates that ejection fraction can be used for predicting the onset of sudden cardiac death episode using trended data. Moreover, even though Levine and Chirife are both drawn from cardiac device arts, Chirife is directed toward bradycardia patients exhibiting too slow heart rhythms, and Levine is directed toward tachycardia patients exhibiting too fast heart rhythms. Thus, Chirife and Levine teach directly away from each other. Accordingly, because all elements of these claims are apparently not disclosed, taught, or suggested by these references, and because there is absolutely no motivation in such references for the combination suggested

by the Examiner (other than the impermissible hindsight of Applicant's own disclosure), Applicant respectfully submits that no proper *prima facie* case of obviousness presently exists with respect to these claims. Therefore, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Concerning claims 8-14, 17, 19:

Applicant has amended claim 8 to include the subject matter of its dependent claim 9. *Applicant respectfully submits that this claim amendment does not raise any new issues that would require further search or consideration because this amendment to claim 8 to include analyzing ejection fraction trend data to predict the onset of a sudden cardiac death episode is already present in independent claim 1 (and as previously-presented dependent claim 9). Therefore, Applicant respectfully submits that this claim amendment raises no new issues.* Applicant respectfully requests withdrawal of the rejection of claims 8-14, 17, 19 for the reasons discussed above with respect to claims 1 and 3.

Concerning claim 29 and 43:

Applicant cannot find in the cited portions of Levine and/or Chirife any disclosure, teaching, or suggestion of monitoring, using the trend data, at least one of a drug regimen, a progress of a congestive heart failure disease condition, and an occurrence of a myocardial infarction, as recited or incorporated in these claims. Moreover, Applicant respectfully notes that this was pointed out in Applicant's previous response, however, cannot find anything in this rejection of the Final Office Action that addresses such distinctions. Accordingly, because all elements of claims 29 and 43 are apparently not disclosed, taught, or suggested by Levine and/or Chirife, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect to such claims. Therefore, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 5, 7, 24-27, 30-42, 44 and 46-49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328). Applicant respectfully traverses.

Concerning claims 5 and 7:

The Office Action states:

Examiner takes the position that Levine et al. inherently teaches of the ability for detecting the difference between resting and non-resting parameters to predict the onset of a sudden cardiac death episode (col. 29 lines 41-48 and claim 46).

(Office Action ¶4.) However, the portion of Levine cited by the Office Action apparently merely pertain to detecting resting and non-resting heart rate—which is not derived from intra-cardiac impedance, as recited in claim 5, but which is instead derived from detecting intrinsic electrical heart signals. (See Levine at col. 7, lines 38-45; col. 8, lines 49-56.) Therefore, the Office Action appears to be improperly ignoring the language in claim 5 by which the physiologic cardiac parameter is derived from intra-cardiac impedance. Because all elements of claims 5 and 7 are apparently not present in Levine, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Concerning claims 24-27, 30-42, 44 and 46-49:

The Office Action states:

Levine et al. also teaches of detecting the occurrence of a myocardial infarction and other cardiac conditions that affect a heart's blood flow (col. 33 lines 13-21). In regards to claims 30, 32, 46, and 48, Examiner takes the position that although Levine et al. does not specifically teach of monitoring for a drug regimen or congestive heart failure, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to include the detection of various cardiac conditions, since this would enhance the system's ability and accuracy in predicting and treating sudden cardiac death, as suggested by Levine et al. in the teaching of monitoring for various cardiac conditions that inherently may effect blood flow (col. 33 lines 13-21).

(Office Action ¶ 4.) However, the cited portion of Levine apparently merely pertain to monitoring intrinsic cardiac activity signals—not a parameter derived from intracardiac impedance, as recited or incorporated in claims 24-27, 30-42, 44 and 46-49. Therefore, the Office Action appears to be improperly ignoring the language in these claims by which the physiologic cardiac parameter is derived from intra-cardiac impedance. Because all elements of these claims are apparently not present in Levine, Applicant respectfully submits that no *prima*

*facie* case of obviousness exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 15 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S. Patent No. 5,154,171) as applied to claims 1-3, 8-14, 17, 19, 29 and 43 above, and further in view of Causey et al. (U.S. Patent No. 4,809,697).

Applicant respectfully traverses on the grounds discussed above with respect to the § 103 rejection of their base claim 8 using Levine and Chirife. Applicant respectfully requests withdrawal of this basis of rejection of these claims.

4. Claims 20-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S. Patent No. 5,154,171) as applied to claims 1-3, 8-14, 17, 19, 29 and 43 above, and further in view of Koestner et al. (U.S. Patent No. 5,300,093).

Applicant respectfully traverses on the grounds discussed above with respect to the § 103 rejection of their base claim 8 using Levine and Chirife. Applicant respectfully requests withdrawal of this basis of rejection of these claims.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

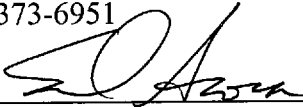
Respectfully submitted,

PAUL V. GOODE JR.

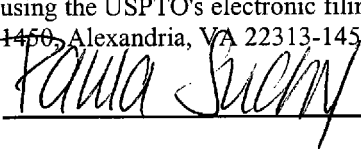
By his Representatives,

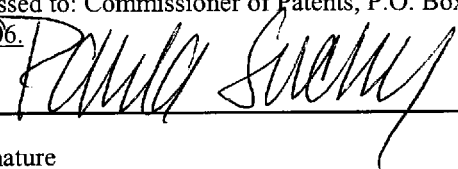
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6951

Date May 22, 2006

By   
Suneel Arora  
Reg. No. 42,267

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22 day of April, 2006.

  
Name

  
Signature